

## REMARKS

Claims 29-52, 54-55, 57 and 59-83 are pending in the application with entry of this amendment. Claims 29 and 67 are currently amended. New claims 80-83 are added. The amendments and new claims do not present new matter. For example, the subject application recites “the catheter 110 and the insulative member 150 form an ‘insulative chamber’ that prevents or minimizes the amount of current that flows through the delivery member 120 when the member 120 is confined to the catheter lumen 112.” Further, as shown in Fig. 1, the delivery member, the insulative member and the temporary connection are arranged in a linear and coaxial manner, and the distal end of the delivery member is joined to the proximal end of the temporary connection, the distal end of the temporary connection is joined to the proximal end of the insulative member, and the distal end of the insulative member is joined to a proximal end of the implant.

Reconsideration and allowance of the application, as amended, are respectfully requested.

### I. Claims 29-35, 38, 43-52, 54, 59-61, 64-65 and 72 Are Patentable Over Wheelock and Ogawa

Independent claim 29 and dependent claims 30-35, 38, 43-52, 54, 59-61, 64-65 and 72 stand rejected under 35 U.S.C. §103(a) as being allegedly being unpatentable over U.S. Patent No. 6,077,260 to Wheelock *et al.* (“Wheelock”) in view of Ogawa. Applicants respectfully traverse the rejection and respectfully submit that the rejection is moot in view of the deficiencies of the cited references.

Wheelock is the primary reference at issue, and cross-sectional view Fig. 1A of Wheelock is reproduced below for reference.

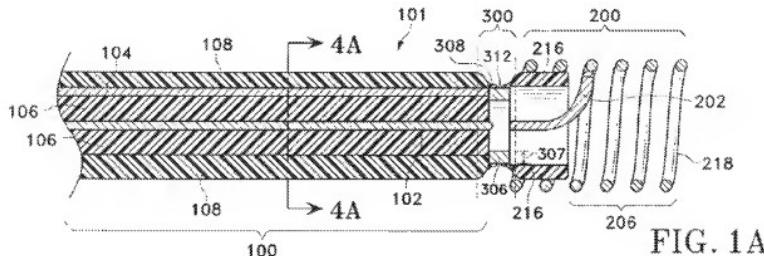


FIG. 1A

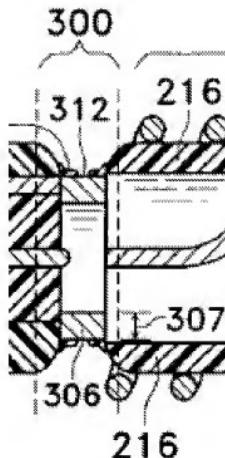
With reference to Wheelock, Fig. 1A above, Wheelock describes a wire assembly 101 having a composite core wire 100, an implant 200 and an electrolytically erodible junction 300 there between. Wheelock (col. 4, lines 20-26). The composite core wire 100 includes a first electrically conductive member 102 and a second electrically conductive member 104. Wheelock (col. 4, lines 33-34 and lines 61-65). “Generally speaking, the electrically conductive member (102) is in electrical contact with implant (200).” Wheelock (col. 4, lines 48-50). The implant 200 is “electrically isolated from the second electrically conductive member (104) and the erodible ring (306) but in electrical contact with first electrically conductive member (102). One way in which this may be accomplished is by the use of a third electrically conductive member (202). This third electrically conductive member (202) is insulated from the second electrically conductive member (104), but is in electrical contact with the first electrically conductive member (102) before implant release, and is in electrical contact with an exposed area (206) of the implant...” Wheelock (col. 5, lines 44-45).

It is stated in the Office Action that Wheelock does not disclose an electrical measurement device that is configured to monitor an electrical condition, such as impedance, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant or the temporary connection being breakable by heat. Office Action (p. 3, para. 1). Thus, it is Applicants’ understanding that the Examiner states that Wheelock fails to disclose “the electrical measurement device is configured to monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the delivery member and joined to the implant through the insulative member, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location as the delivery member is advanced through the catheter, the electrical measurement device configured to generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating that the temporary connection, joined to the implant, has reached the predetermined location” as recited in claim 29.

Wheelock does not disclose a structural configuration of components that are joined together as recited in claim 29, *i.e.*, that “the distal end of the delivery member is joined to the proximal end of the temporary connection, the distal end of the temporary connection is joined to a proximal end of the insulative member, and the distal end of the insulative member is joined to

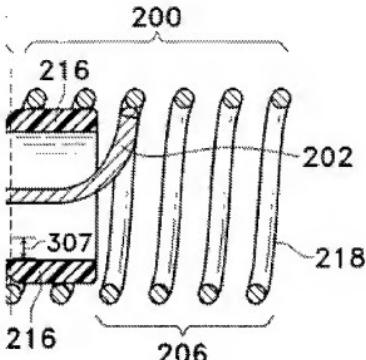
a proximal end of the implant" and "such that the catheter and the insulative member form an insulative chamber that inhibits current that flows through the delivery member when the delivery member is confined to the lumen" as recited in claim 29, noting that claim 29 is also amended to recite that the delivery member is conductive.

It is alleged in the Office Action, p. 2, para. 2, that the core wire 100 is a "delivery member," the insulating layer 216 is an "insulative member," and the junction 300 is a "temporary connection" as recited in claim 29. However, the Office Action has cited no section of Wheelock that discloses a distal end of the junction 300 (alleged "temporary connection") "joined to" a proximal end of the insulating layer 216 (alleged "insulative member"). Rather, upon closer inspection of Wheelock, Fig. 1A (an exploded portion of which is provided below), the distal end of the top portion of the erodible ring 306 appears to be below the bottom edge of the top portion of the insulating layer 216, and the distal end of the bottom portion of the erodible ring 306 appears to be above the top edge of the bottom portion of the insulating layer 216.



Thus, in addition to failing to disclose that the erodible ring 306 is "joined to" the insulating layer 216, Fig. 1A appears to illustrate that these two components may not even contact each other. The Office Action has not established that mere proximity of components results in those components being "joined" together, particularly in view of what is actually shown by Wheelock.

Wheelock does not disclose the distal end of the insulating layer 216 (alleged “insulative member”) is “joined to” a proximal end of the implant 200. Rather, upon closer inspection of Fig. 1A above (an exploded portion of which is provided below), the distal ends of both the top and bottom portions of the insulating layer 216 (alleged “insulative member”) are not “joined to” the implant 200 and the implant 200 does not extend from a distal end of the layer 216.



Rather, as shown above, the distal end of the insulating layer 216 does not contact the coil 218, which instead, wraps around an outer surface of the insulating layer 216. Consequently, the distal portion of the insulating layer 216 is not “joined to” the proximal portion of an implant since, at a minimum, the distal end of the insulating layer 216 does not contact the coil 218. In this regard, Wheelock describes a configuration that is the opposite of the configuration recited in claim 29, particularly considering that the coil wraps around an outer surface of the insulating layer rather than being joined to and extending from a distal end of the insulating layer.

Additionally, Wheelock does not disclose “such that the catheter and the insulative member form an insulative chamber that inhibits current that flows through the delivery member when the delivery member is confined to the lumen” as recited in claim 29. As discussed above, a portion of the conductive coil 218 is wrapped around an outer surface of the insulative layer 216. Consequently, when such a device is inserted into a catheter, the insulative layer 216 would not even contact an inner surface of the catheter such that the catheter and the cited insulative layer would not form an insulative chamber due to the intervening conductive coil 218. In this regard, Wheelock describes a structural configuration that is the opposite of the configuration

recited in claim 29, particularly considering that Wheelock explains “The entire distal portion of the coil (218) serves as the exposed area (206), as it is indirect electrical contact with surrounding body fluids” and the purpose of the insulating layer 216 is to electrically isolate the coil implant 218 from the second electrically conductive member (within the core wire 100). Wheelock (col. 5, lines 55-60).

Further, as noted in Applicants’ prior response, the Office action refers to the insulating layer 216 and an implant (presumably implant 200) as different components, but Wheelock illustrates and explains that the implant 200 includes (as shown by the top right bracket in Fig. 1) a coil 218 having an exposed area 206, the insulating layer 206 and an electrically conductive member 202. Thus, the insulating layer 206 is actually part of the implant 200, which is consistent with Fig. 1A showing the insulating layer 206 along sections of the coil 218, which is also part of the implant 200. Also consistent with this conclusion is Wheelock explaining “FIGS. 1A-1C depict a preferred coil implant (218) which has an insulating layer (216)...” Wheelock (col. 5, lines 55-57).

Wheelock also describes different components for joining the core wire 100 (alleged “delivery member”) and the implant 200. For example, Wheelock explains that the implant 200 and the core wire 100 are in contact with each other when the junction 300 there between is intact, and the protruding distal end of the first electrically conductive member 102 is in contact with a surface 208 of a third electrically conductive member 202. Wheelock (col. 5, line 59 – col. 6, line 10). Notably, this section does not mention the insulating layer 216, consistent with the fact that the insulating layer 216 is used for a different and unrelated purpose, *i.e.*, to electrically isolate the coil 218 from a second electrically conductive member, and as discussed above, the Office Action has failed to demonstrate that mere proximity of two components means they are joined together, particularly if those two components may not even contact each other.

In view of these differences and the particular structural configuration of the insulative “layer” 216 and since the coil 218 is wrapped around an outer surface thereof, Wheelock teaches away from limitations directed to the distal end of the temporary connection is joined to a proximal end of the insulative member, and the distal end of the insulative member is joined to a proximal end of the implant as recited in claim 29.

Thus, while Applicants appreciate that Wheelock may disclose components that have similar names, the structure that is actually disclosed by Wheelock does not support the rejection of claim 29, which recites a structural configuration that renders Wheelock moot.

It is conceded that Ogawa fails to disclose certain structural configurations recited in claim 29. Office Action (p. 14). Remarks that remain applicable to claim 29 as amended and various dependent claims are discussed in the prior amendment are not repeated.

Ogawa is cited as allegedly disclosing an electrical measurement device that is configured to monitor an electrical condition related to a position of a temporary connection while the temporary connection is joined to the delivery member and to the implant. Ogawa, however, does not cure the substantial deficiencies of Wheelock discussed above and has its own deficiencies.

Further, the Office Action refers to Ogawa, col. 7, line 54 – col. 8, line 6 as allegedly disclosing an output signal provided to the user while the temporary connection is joined to the implant when the implant reaches the pre-determined position to allow the user to manually initiate breaking of the temporary connection. The cited section of Ogawa, however, does not support the Office Action allegations. The cited section of Ogawa explain that when the distal end of the guide wire 10 is situated at the distal opening of the catheter 20, the impedance by the high-frequency voltage for measurement generally reduces rapidly, thereby detecting the fact that the implanted device 16 has been deposited properly in the patient's body. Ogawa then explains "In this state, a monopolar high-frequency current for detaching the implanted device is applied between the guide wire and the counter electrode 23 by the high frequency power source 24" with the result that the joint member 15 is heated, melted and severed. This section of Ogawa, while discussing detection of impedance, nevertheless fails to disclose the electrical measurement device configured to generate an output signal while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating that the temporary connection, joined to the implant, has reached the predetermined location as recited in claim 1.

In view of these deficiencies and differences, Applicants respectfully submit that independent claim 29 is patentable over Wheelock and Ogawa since no proper combination of the cited references discloses each limitation of claim 29. Dependent claims 30-35, 38, 43-52, 54, 59-61, 64-65 and 72 incorporate the elements of claim 29 and, therefore, are also believed

patentable over Wheelock and Ogawa, which is also deficient relative to various dependent claims.

Accordingly, Applicants respectfully submit that the rejection of claims 29-35, 38, 43-52, 54, 59-61, 64-65 and 72 under 35 U.S.C. §103(a) be withdrawn.

**III. Claims 36, 41-42, 55, 57 and 66 Are Patentable Over Wheelock, Ogawa and Scheldrup**

Dependent claims 36, 41-42, 55, 57 and 66 (which depend from independent claim 29), stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Scheldrup. Scheldrup, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and the rejected dependent claims.

Accordingly, Applicants respectfully submit that the rejection of claims 36, 41-42, 55, 57 and 66 under 35 U.S.C. §103(a) be withdrawn.

**IV. Claim 37 Is Patentable Over Wheelock, Ogawa and Palermo**

Dependent claim 37 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Palermo. Palermo, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 37.

Accordingly, Applicants respectfully submit that the rejection of claim 37 under 35 U.S.C. §103(a) be withdrawn.

**V. Claim 39 Is Patentable Over Wheelock, Ogawa and Guglielmi**

Dependent claim 39 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Guglielmi. Guglielmi, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 39.

Accordingly, Applicants respectfully submit that the rejection of claim 39 under 35 U.S.C. §103(a) be withdrawn.

**VI. Claim 40 Is Patentable Over Wheelock, Ogawa and Sepetka**

Dependent claim 40 (which depends from independent claim 29), stands rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Sepetka. Sepetka, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claim 40.

Accordingly, Applicants respectfully submit that the rejection of claim 40 under 35 U.S.C. §103(a) be withdrawn.

**VII. Claims 62-63 Are Patentable Over Wheelock, Ogawa and Cheng**

Dependent claims 62-63 (which depend from independent claim 29), stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Cheng. Cheng, however, does not cure the substantial deficiencies of Wheelock and Ogawa discussed above. Consequently, no proper combination of these three references discloses each limitation of independent claim 29 and claims 62-63.

Accordingly, Applicants respectfully submit that the rejection of claims 62-63 under 35 U.S.C. §103(a) be withdrawn.

**VIII. Claims 67-71 and 73 Are Patentable Over Wheelock, Ogawa and Scheldrup**

Independent claim 67 and dependent claims 68-71 and 73 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Wheelock in view of Ogawa and further in view of Scheldrup. Applicants respectfully submit that the rejection is moot in view of the above remarks.

Accordingly, Applicants respectfully submit that the rejection of claims 67-71 and 73 under 35 U.S.C. §103(a) be withdrawn.

**IX. New Claims 80-83**

Claims 80-83 depend from respective independent claims 29 and 69 and, therefore, are also believed patentable over the cited references. Various cited references are also deficient relative to these claims.

Claims 80 and 81 recite *inter alia* “wherein the delivery member, the insulative member and the temporary connection are linearly and coaxially arranged within the lumen of the catheter.” In contrast, the components of Wheelock cited in the Office Action are not linearly arranged. For example, the erodible ring 306 and the insulative layer 216, while in proximity to each other, are not arranged in a linear manner since they are offset from each other.

Claims 82 and 83 recite *inter alia* “wherein the insulative chamber defined by the catheter and the insulative member prevents or minimizes the amount of current that flows through the delivery member when the delivery member is confined to the catheter lumen.” Wheelock discloses no such configuration, particularly considering that Wheelock discloses that the proximal portion of the coil 218 is wrapped around an outer surface of the insulative layer 216 (alleged “insulative element”).

### CONCLUSION

Applicants respectfully submit that the application is in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicants invite the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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Dated: March 22, 2010

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